Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently amended) A process for producing parenterally administrable microparticles containing a biologically active substance, which process comprises:

a) preparing an aqueous solution of the biologically active substance to be incorporated in the microparticles;

b) mixing the solution obtained in step a) with an aqueous solution of polyethylene glycol to form a concentrated biologically active substance, said concentrated biologically active substance selected from a concentrated solution of the biologically active substance or a solid particle precipitate of the biologically active substance;

c) optionally washing the concentrated biologically active substance obtained in step b);

d) mixing the concentrated biologically active substance obtained in step b) or step c) with an aqueous starch solution to form a composition comprising the concentrated biologically active substance and the starch solution;

e) mixing the composition obtained in step d) with an aqueous solution of a polymer having the ability to form a two-phase aqueous system comprising an emulsion of starch droplets which contain the biologically active substance as the inner phase in an outer phase of the polymer solution;

f) causing or allowing the starch droplets obtained in step e) to solidify into starch microparticles;

g) drying the solid starch microparticles from step f); and

h) ~~optionally~~ coating the dried solid starch microparticles from step g) with a release controlling shell of a biocompatible and biodegradable polymer.

2. (Previously presented) The process according to claim 1, in which step b) is performed such that the biologically active substance precipitates from the aqueous solution obtained in step a) to form solid particles.

3. (Previously presented) The process according to claim 1, in which step b) is performed

such that a concentrated solution of the biologically active substance is formed, wherein the concentrated solution has a viscosity that differs from the viscosity of the solution obtained step a) and the ability to form droplets which can be handled at room temperature.

4. (Previously presented) The process according to claim 1, wherein the biologically active substance of step b) is restored to essentially the same chemical and biological form as said biologically active substance prior to concentration or precipitation.

5. (Previously presented) The process according to claim 1, in which the concentrated solution of biologically active substance forms a pellet or a solution of higher viscosity than the concentrated solution or solid bottom phase in centrifugation or ultracentrifugation.

6. (Previously presented) The process according to claim 1, in which the polyethylene glycol used in step b) has an average molecular weight of 400 to 100,000 Da.

7. (Previously presented) The process according to claim 1, in which the concentration of the polyethylene glycol used in step b) is in the range of 1-50 % (w/w).

8. (Previously presented) The process according to claim 1, in which, in step d), an aqueous starch solution is utilized, comprising starch which has an amylopectin content exceeding 85 % by weight, in which the molecular weight of the said amylopectin has been reduced such that at least 80% by weight of the material lies within the range of 10-10,000 kDa.

9. (Previously presented) The process according to claim 1, in which, in step d), an aqueous starch solution is utilized, comprising starch which has an amino acid nitrogen content of less than 50 μg per gram dry weight of starch.

10. (Previously presented) The process according to claim 1, in which the starch concentration of the aqueous starch solution used in step d) is at least 20 % by weight.

11. (Previously presented) The process according to claim 8, in which the starch has a purity of at most 20 μg amino acid nitrogen per gram dry weight of starch.

12. (Previously presented) The process according to claim 8, in which the starch has an

amylopectin content with said reduced molecular weight exceeding 95 % by weight.

13. (Previously presented) The process according to claim 8, in which the molecular weight of said amylopectin has been reduced such that at least 80% by weight of the material lies within the range of 100-4000 kDa.

14. (Previously presented) The process according to claim 1, in which the starch is such that it can only be dissolved to a concentration exceeding 25 % by weight in water.

15. (Previously presented) The process according to claim 1, in which the starch lacks covalently bonded extra chemical groups which are found in hydroxyethyl starch.

16. (Previously presented) The process according to claim 1, in which the starch has an endotoxin content of less than 25 EU/g and contains less than 100 microorganisms per gram.

17. (Previously presented) The process according to claim 1, in which the starch is essentially purified from surface-located proteins, lipids and endotoxins by means of washing with an aqueous alkali solution and purified from internal proteins by means of ion-exchange chromatography.

18. (Previously presented) The process according to claim 8, in which, in step d), 215% by weight amylose is also used as starch, having an average molecular weight within the range of 2.5-70 kDa in which the percentage by weight is calculated on the basis of dry weight starch.

19. (Previously presented) The process according to claim 8, in which, in step d), a solution is prepared having a starch concentration of at least 30% by weight.

20. (Previously presented) The process according to claim 8, in which, in step d), a solution is prepared having a starch concentration of at most 50% by weight.

21. (Previously presented) The process according to claim 8, in which the aqueous starch solution in step d) is prepared with accompanying autoclaving.

22. (Previously presented) The process according to claim 1, in which, in step d), the active substance is combined with the starch solution at a temperature of at most 60°C.

23. (Previously presented) The process according to claim 1, in which, in step d), the weight ratio between starch and biologically active substance in the composition lies within the range of 3:1 to 10000:1.

24. (Previously presented) The process according to claim 1, in which the mixing in step e) is performed at a temperature within the range of 4-50°C.

25. (Previously presented) The process according to claim 1, in which the mixing in step e) is performed by means of at least one static mixer.

26. (Previously presented) The process according to claim 1, in which, in step e), the polymer solution is added to the composition in at least two steps, at least one of the addition steps being effected after the emulsion has begun to be created.

27. (Previously presented) The process according to claim 1, in which, in step e), polyethylene glycol is used as the aqueous polymer.

28. (Previously presented) The process according to claim 27, in which the polyethylene glycol has an average molecular weight of 5-35 kDa.

29. (Previously presented) The process according to claim 1, in which, in step e), starch droplets are formed which yield microparticles comprising a mean particle diameter size within the range of 10-200 μm, in the dry state.

30. (Previously presented) The process according to claim 29, in which, after step e), the microparticles are washed through filtration and optionally sieved in order to obtain the desired particle size distribution.

31. (Previously presented) The process according to claim 1, in which the solidification in step f) is effected at at least two temperatures, in which initiation of solidification is effected at a lower temperature than termination of solidification.

32. (Previously presented) The process according to claim 31, in which the solidification in step f) is initiated within the range of 1-20°C, and is terminated within the range of 20 to 55°C.

33. (Previously presented) The process according to claim 1, in which the drying in step g) is performed in the form of spray-drying, freeze-drying, or vacuum-drying.

34. (Previously presented) The process according to claim 1, in which the biologically active substance comprising the microparticles comprises one or more of proteins, peptides, polypeptides, polynucleotides, or polysaccharides.

35. (Previously presented) The process according to claim 1, in which the application of the release-controlling shell in step h) is performed by means of air suspension technology.

36. (Previously presented) The process according to claim 1, in which the release-controlling shell in step h) comprises a homopolymer or copolymer containing alpha-hydroxy acid units.

37. (Previously presented) The process according to claim 36, in which the alpha-hydroxy acid is lactic acid and/or glycolic acid.

38.-59. (Cancelled)

60. (Previously presented) The process according to claim 7, in which the concentration of the polyethylene glycol used in step b) is in the range of 2-45 % (w/w).

61. (Previously presented) The process according to claim 7, .in which the concentration of the polyethylene glycol used in step b) is in the range of 10-40 % (w/w).

62. (Previously presented) The process according to claim 7, in which the concentration of the polyethylene glycol used in step b) is in the range of 20-30 % (w/w).

63. (Previously presented) The process according to claim 11, in which he starch has a purity of at most 10 μg amino acid nitrogen per gram dry weight of starch.

64. (Previously presented) The process according to claim 11, in which the starch has a purity of at most 5 μg amino acid nitrogen per gram dry weight of starch.

65. (Previously presented) The process according to claim 12, in which the starch has an

amylopectin content with said reduced molecular weight exceeding 98 % by weight.

66. (Previously presented) The process according to claim 13, in which the molecular weight of said amylopectin has been reduced such that at least 80 % by weight of the amylopectin lies within the range of 200- 1000 kDa.

67. (Previously presented) The process according to claim 13, in which the molecular weight of said amylopectin has been reduced such that at least 80% by weight of the amylopectin lies within the range of 300-600 kDa.

68. (Previously presented) The process according to claim 18, in which, in step d), 215 % by weight amylose is also used as starch, having an average molecular weight within the range of 5-45 kDa in which the percentage by weight is calculated on the basis of dry weight starch.

69. (Previously presented) The process according to claim 20, in which, in step d), a solution is prepared having a starch concentration of at most 45 % by weight.

70. (Previously presented) The process according to claim 22, in which, in step d), the active substance is combined with the starch solution at a temperature of 20-45°C.

71. (Previously presented) The process according to claim 22, in which, in step d), the active substance is combined with the starch solution at a temperature of 30-37°C.

72. (Previously presented) The process according to claim 24, in which the mixing in step e) is performed at a temperature within the range of 10-40°C.

73. (Previously presented) The process according to claim 24, in which the mixing in step e) is performed at a temperature within the range of 10-37°C.

74. (Previously presented) The process according to claim 28, in which the polyethylene glycol has an average molecular weight of 15-25 kDa.

75. (Previously presented) The process according to claim 28, in which the polyethylene glycol has an average molecular weight of about 20 kDa.

76. (Cancelled)

77. (Previously presented) The process according to claim 29, in which, in step e), starch droplets are formed which yield microparticles comprising a size within the range of 20-100 μm, in the dry state.

78. (Previously presented) The process according to claim 29, in which, in step e), starch droplets are formed which yield microparticles comprising a size within the range of 20-80 μm, in the dry state.

79. (Previously presented) The process according to claim 32, in which the solidification is initiated within the range of 1-10°C, and is terminated within the range of 20-55°C.

80. (Previously presented) The process according to claim 32, in which the solidification is initiated around 4°C, and is terminated within the range of 20-55°C.

81. (Previously presented) The process according to claim 32, in which the solidification is initiated within the range of 1-20°C, and is terminated within the range of 20-40°C.

82. (Previously presented) The process according to claim 32, in which the solidification is initiated within the range of 1-20°C, and is terminated around 37°C.

83. (Previously presented) The process according to claim 33, in which the drying in step g) is performed by freeze-drying.

84. (Previously presented) The process according to claim 34, wherein the protein is a recombinantly produced protein.

85. (Previously presented) The process according to claim 1, in which the polyethylene glycol used in step b) has an average molecular weight of 4,000 to 35,000 Da.

86. (Previously presented) The process according to claim 1, in which the polyethylene glycol used in step b) has an average molecular weight of 6,000 to 20,000 Da.

87. (Previously presented) The process according to claim 1, in which the polyethylene glycol used in step b) has an average molecular weight of about 20,000 Da.

88. (Previously presented) The process according to claim 17, in which the ion-exchange chromatography is anion exchange chromatography.

89. (Previously presented) The process according to claim 34, wherein the protein is human growth hormone (hGH).

90. (Previously presented) The process according to claim 1, wherein, in step (h), the biocompatible and biodegradable polymer comprises polymers of lactic acid and glycolic acid (PLGA).

91. (Previously presented) The process according to claim 1, wherein, in step (h), the biocompatible and biodegradable polymer is applied as a coating by air suspension technology.

92. (Previously presented) The process according to claim 1, wherein, in step (h), the biocompatible and biodegradable polymer is applied in the presence of an organic solvent.

93. (Currently amended) A process for producing parenterally administrable microparticles containing a biologically active substance, which process comprises:

a) preparing an aqueous solution of the biologically active substance to be incorporated in the microparticles;

b) mixing the solution obtained in step a) with an aqueous solution of polyethylene glycol to form a concentrated biologically active substance, said concentrated biologically active substance selected from a concentrated solution of the biologically active substance or a solid particle precipitate of the biologically active substance;

c) optionally washing the concentrated biologically active substance obtained in step b);

d) mixing the concentrated biologically active substance obtained in step b) or step c) with an aqueous starch solution to form a composition comprising the concentrated biologically active substance and the starch solution;

e) mixing the composition obtained in step d) with an aqueous solution of a polymer having the ability to form a two-phase aqueous system comprising an emulsion of starch droplets which contain the biologically active substance as the inner phase in an outer phase of the polymer solution;

f) causing or allowing the starch droplets obtained in step e) to solidify into starch microparticles; wherein solidification is effected at at least two temperatures, with initiation of solidification being at a lower temperature than termination of solidification;

g) drying the solid starch microparticles from step f); and

h) ~~optionally coating the dried solid starch microparticles from step g) by air-suspension technology with a release controlling shell comprising biocompatible and biodegradable polymer of lactic acid and glycolic acid (PLGA)~~ coating the dried solid starch microparticles from step g) with a release controlling shell of a biocompatible and biodegradable polymer.

94. (Previously presented) A process for producing parenterally administrable microparticles containing a biologically active substance, which process comprises:

a) preparing an aqueous solution of the biologically active substance to be incorporated in the microparticles;

b) mixing the solution obtained in step a) with an aqueous solution of polyethylene glycol to form a concentrated biologically active substance, said concentrated biologically active substance selected from a concentrated solution of the biologically active substance or a solid particle precipitate of the biologically active substance;

c) optionally washing the concentrated biologically active substance obtained in step b);

d) mixing the concentrated biologically active substance obtained in step b) or step c) with an aqueous starch solution to form a composition comprising the concentrated biologically active substance and the starch solution;

e) mixing the composition obtained in step d) with an aqueous solution of a polymer having the ability to form a two-phase aqueous system comprising an

emulsion of starch droplets which contain the biologically active substance as the inner phase in an outer phase of the polymer solution;

f) causing or allowing the starch droplets obtained in step e) to solidify into starch microparticles;

g) drying the solid starch microparticles from step f); and

h) coating the dried solid starch microparticles from step g) by air suspension technology with a release controlling shell comprising biocompatible and biodegradable polymer of lactic acid and glycolic acid (PLGA).

95. (Previously presented) The process according to claim 93 wherein, in step (h), the biocompatible and biodegradable polymer comprises polymers of lactic acid and glycolic acid (PLGA).

96. (Previously presented) The process according to claim 94 wherein, in step (h), the biocompatible and biodegradable polymer of lactic acid and glycolic acid (PLGA) is applied in the presence of an organic solvent.

97. (New) The process according to claim 93, in which the solidification in step f) is initiated within the range of 1-20°C, and is terminated within the range of 20 to 55°C.

98. (New) The process according to claim 93, in which the solidification is initiated within the range of 1-10°C, and is terminated within the range of 20-55°C.

99. (New) The process according to claim 93, in which the solidification is initiated within the range of 1-20°C, and is terminated within the range of 20-40°C.

100. (New) The process according to claim 93, in which the solidification is initiated within the range of 1-20°C, and is terminated around 37°C.

101. (New) The process according to claim 93, in which the solidification is initiated around 4°C, and is terminated within the range of 20-55°C.

102. (New) The process according to claim 93, in which the drying in step g) is performed in the form of spray-drying, freeze-drying, or vacuum-drying.

103. (New) The process according to claim 93, in which the biologically active substance comprising the microparticles comprises one or more of proteins, peptides, polypeptides, polynucleotides, or polysaccharides.

104. (New) The process according to claim 103, wherein the protein is a recombinantly produced protein.

105. (New) The process according to claim 93, in which the application of the release-controlling shell in step h) is performed by means of air suspension technology.

106. (New) The process according to claim 93, in which the release-controlling shell in step h) comprises a homopolymer or copolymer containing alpha-hydroxy acid units.

107. (New) The process according to claim 93, in which the alpha-hydroxy acid is lactic acid and/or glycolic acid.

108. (New) The process according to claim 93, in which the concentration of the polyethylene glycol used in step b) is in the range of 1-50 % (w/w).

109. (New) The process according to claim 93, in which the molecular weight of said amylopectin has been reduced such that at least 80 % by weight of the amylopectin lies within the range of 200-1000 kDa.

110. (New) The process according to claim 93, in which, in step d), the active substance is combined with the starch solution at a temperature of 20- 45°C.

111. (New) The process according to claim 93, in which the mixing in step e) is performed at a temperature within the range of 10-40°C.

112. (New) The process according to claim 93, in which the polyethylene glycol has an average molecular weight of 15-25 kDa.

113. (New) The process according to claim 93, in which, in step e), starch droplets are formed which yield microparticles comprising a size within the range of 20-100 μm, in the dry state.